

U.S. Patent Appln. S.N. 10/534,988
REQUEST FOR RECONSIDERATION

PATENT

See the attached Declaration of Professor Gail McMillan, which demonstrates the Prater Dissertation was not publicly available until after the March 14, 2003 priority date of this application.

Applicants' claim to foreign priority of March 14, 2003 has already been perfected. Their Finnish priority application was originally filed in English, and the International Bureau provided a copy to the U.S. Patent and Trademark Office.

The Prater Dissertation is not prior art to the claimed method because it was not publicly accessible from the Virginia Tech database until after the applicants' priority date. See In re Lister, 583 F.3d 1307, 92 USPQ2D 1225 (Fed. Cir. 2009) (Manuscript not publicly accessible, and thus not a reference, in absence of evidence showing it was publicly available from database prior to critical date). Reconsideration and withdrawal of the obviousness rejection of claims 31-36 over Prater and Wille '979 are respectfully requested.

The 35 U.S.C. § 103(a) rejection of claims 31-36 over Wille '979 is also traversed. The claimed method for treatment of a local inflammatory disease or disorder includes administering a pharmaceutical composition to a person or animal in need thereof, the pharmaceutical composition consisting

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essentially of an active substance, the active substance consisting of a pharmaceutically acceptable agent or salt thereof capable of acidifying cell cytoplasm, the agent being an acid having a dissociation constant, expressed as its negative logarithm pKa, in the range of 6.7 to 7.4. Importantly, the pharmaceutical composition has a pH range in the range of 6.1 to 7.0, and the pharmaceutically acceptable agent is an organic acid having a specified heterocyclic ring. Cis-urocanic acid is a suitable pharmaceutically acceptable agent.

Wille '979 fails to raise a prima facie case of obviousness against the claimed method because one of ordinary skill in the art is given no motivation or suggestion to modify the Wille '979 composition by selecting a pH for its composition of 6.1 to 7.0. Instead, Col. 12, lines 64-66 suggest optionally buffering preparations which contain cis-urocanic acid to pH "between 1 and 12". Such a broad pH range simply does not disclose or suggest the claimed pH composition range of 6.1 to 7.0.

The Patent Office argument that Wille '979 renders the claimed composition obvious because its pH 1-12 range overlaps the applicants' pH range of 6.1 to 7.0 is without merit where, as here, the logarithmic nature of the pH 1-12 range is so broad as to be

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almost meaningless. In other words, any aqueous composition will have a pH of from 1 to 14; the pH range of Wille '979 (1 to 12) simply does not suggest a pH range of 6.1 to 7.0.

Example 3 of Wille '979 discloses cis-UCA compositions having a pH of 5.5 (Table III) or 7.2 (Table IV). Again, one of ordinary skill is given no disclosure or suggestion to modify these Wille '979 compositions so that they have a pH of from 6.1 to 7.0

Wille '979's suggested pH 1-12 range shows they did not recognize the acid dissociation properties of cis-UCA are important to its immunosuppressive properties. In this regard, the Examiner's attention is directed to the attached Declaration of Dr. Jarmo Laihia, which reports a series of cell studies to demonstrate the superiority of the claimed pH range in comparison to pH 5.5 and 7.4.

Reconsideration and withdrawal of the obviousness rejection of claims 31-36 over Wille '979 are requested.

It is believed this application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 31-36, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the

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undersigned should he believe any further action is required for allowance.

The RCE filing fee and extension of time fee are being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Request for Reconsideration. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

James C. Lydon
Reg. No. 30,082

Atty. Case No.: **OHMAN-002**
100 Daingerfield Road
Suite 100
Alexandria, Virginia 22314
Telephone: (703) 838-0445
Facsimile: (703) 838-0447

Enclosures:

Petition for Extension of Time
Request for Continued Examination
Declaration of Prof. Gail McMillan
Declaration of Dr. Jarmo Laihia